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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,466	03/26/2004	Ming H. Wu	MEM-0004	1783

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EXAMINER	
HORNBERGER, JENNIFER LEA	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
08/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/811,466	WU ET AL.	
	Examiner	Art Unit	
	JENNIFER L. HORNBERGER	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-21 and 31-43* is/are pending in the application.

4a) Of the above claim(s) *31-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 6-21, and 31-42 are pending. Claims 31-42 are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12, 13, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites the biodegradable polymeric resin is a thermoplastic resin, wherein the "thermoplastic resin is polyacetal, polyacrylic, polycarbonate, polystyrene, polyethylene, polypropylene, polyethylene terephthalate, polybutylene terephthalate, polyamide, polyamideimide, polybenzimidazole, polybenzoxazole, polybenzothiazole, polyoxadiazole, polythiazole, polyquinoxaline, polyimidazopyrrolone, polyarylate, polyurethane, polyarylsulfone, polyethersulfone, polyphenylene sulfide, polyvinyl chloride, polysulfone, polyetherimide, polytetrafluoroethylene, fluorinated ethylene propylene, perfluoroalkoxy polymer, polychlorotrifluoroethylene, polyvinylidene fluoride, polyvinyl fluoride, polyetherketone, polyether etherketone, polyether ketone ketone or a combination comprising at least one of the foregoing thermoplastic resins." However, thermoplastic resins such as polyvinyl chloride, polystyrene, tetrafluoroethylene, fluorinated ethylene propylene are not biodegradable polymers. The language of claim 12 is inconsistent with claim 1 which requires the resin be formed of a biodegradable polymer. Applicant should amend claim 12 to remove any polymer which is not biodegradable. Similarly, claim 13 recites the biodegradable polymeric resin is a thermosetting resin, wherein the "thermosetting resin is polyurethane, natural rubber, synthetic rubber, epoxy, phenolic, polyester, polyamide, silicone, or a combinations comprising at least one of the foregoing thermosetting resin. As least silicone is not considered to be

biodegradable. Applicant should amend claim 13 to remove polymers which are not biodegradable.

4. Claim 16 recites the limitation "..agents are dispersed within the polymeric resin". Claim 17 recites the limitation "..agents are encapsulated between layers of polymeric resins". Each of these limitations is mutually exclusive with independent claim 1, wherein the agents are required to be covalently bonded to the polymeric resin, according to paragraph 33 of applicant's disclosure.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 6, 10-15, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) in view of Carpenter et al. (US 2004/0170685).

Regarding claim 1, Eum al. disclose a medical device comprising: a nickel-titanium based shape memory alloy having a reverse martensitic transformation start temperature (A_s) of about 10 degrees Celsius to about 20 degrees Celsius; and a transformation start temperature of (A_f) of about 30 degrees Celsius plus or minus 5 degrees Celsius (paragraph 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum ranges for both the transformation start and transformation finish temperatures, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Eum et al. fail to disclose a drug coating comprising a polymeric

resin and one or more biologically active agents. Carpenter et al. disclose coating a metal stent (paragraphs 99 and 102) with a drug coating comprising a biodegradable polymer having covalently bonded biologically active agents (paragraphs 22, 39, 40) to promote healing processes at the site of stent implantation (paragraph 21). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Eum et al. with the drug coating comprising biodegradable polymer having covalently bonded biologically active agents as taught by Carpenter et al. to deliver drugs locally to the vessel for example to promote healing at the implantation site.

Regarding claim 6, Eum et al. disclose the nickel-titanium based alloy is a binary nickel-titanium alloy, nickel-titanium-niobium alloy, nickel-titanium-copper alloy, nickel-titanium-iron alloy, nickel-titanium-hafnium alloy, nickel-titanium-palladium alloy, nickel-titanium-gold alloy, nickel-titanium-platinum alloy, or comprising at least one of the foregoing nickel-titanium based alloys (paragraph 10).

Regarding claim 10, Carpenter et al. fail to disclose the glass transition temperature of the biodegradable polymer. Applicant discloses the polymer resin used in the drug coating has a glass transition temperature less than or equal to the reverse martensitic transformation start temperature, and further discloses a list of appropriate biodegradable polymers. Carpenter et al. discloses using the same biodegradable materials as applicant. The materials disclosed by Carpenter et al. are understood to meet the limitation of having a glass transition temperature less than or equal to the reverse martensitic transformation temperature, since glass transition temperature is a material property.

Regarding claims 11-13, Carpenter et al. disclose the polymeric resin is a thermoplastic resin, a thermosetting resin, or a blend of a thermoplastic resin with a thermosetting resin, wherein the thermoplastic resin is polyacetal, polyacrylic, polycarbonate, polystyrene,

polyethylene, polypropylene, polyethylene terephthalate, polybutylene terephthalate, polyamide, polyamideimide, polybenzimidazole, polybenzoxazole, polybenzothiazole, polyoxadiazole, polythiazole, polyquinoxaline, polyimidazopyrrolone, polyarylate, polyurethane, polyarylsulfone, polyethersulfone, polyphenylene sulfide, polyvinyl chloride, polysulfone, polyetherimide, polytetrafluoroethylene, fluorinated ethylene propylene, perfluoroalkoxy polymer, polychlorotrifluoroethylene, polyvinylidene fluoride, polyvinyl fluoride, polyetherketone, polyether etherketone, polyether ketone or a combination comprising at least one of the foregoing thermoplastic resins, and wherein the thermosetting resin is a polyurethane, natural rubber, synthetic rubber, epoxy, phenolic, polyester, polyamide, silicone, or a combinations comprising at least one of the foregoing thermosetting resin (paragraphs 58-59 and 76-77).

Regarding claim 14, Carpenter et al. discloses the drug coating comprises an amount of about .1 weight percent to about 99.9 weight percent of the biologically active agent based on total weight of the drug coating (paragraphs 187-188). Carpenter et al. disclose the claimed invention except for the drug coating comprising an amount of about 5 weight percent to about 90 weight percent of the biologically active agent based on the total weight of the drug coating. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum amount of the biologically active agent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 15, Carpenter et al. disclose the biologically active agents are copolymerized with the polymeric resin.

Regarding claim 19, Carpenter et al. disclose wherein the biodegradable polymer is a polylactic-glycolic acid, poly-caprolactone, copolymer of polylactic-glycolic acid and poly-caprolactone, polyhydroxy-butyrate-valerate, polyorthoester, polyethyleneoxide-butylene

terephthalate, poly-D,L-lactic acid-p-dioxanone-polyethylene glycol block copolymer or a combination comprising at least one of the foregoing biodegradable polymers (paragraphs 58, 59, 76 and 77).

Regarding claims 20 and 21, Eum et al. disclose the implantable device is a stent, bone staple, a vena cava filter, a suture, or an anchor-like mechanism (paragraph 1).

1. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) and Carpenter et al. (US 2004/0170685) as applied to claim 1 above, and further in view of Simpson et al. (US 4,770,725).

Regarding claims 7 and 9, Eum et al. discloses the claimed invention except for the nickel-titanium based alloy containing niobium. Simpson et al. disclose a shape memory alloy consisting of nickel, titanium, and niobium (see abstract) . It would have been obvious to one of ordinary skill to substitute the shape memory alloy of Eum et al. with shape memory alloy of Simpson et al. to provide self-expanding property to a stent. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention. As to the compositions of the nickel-titanium-niobium allow, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum nickel and niobium compositions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

2. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) and Carpenter et al. (US 2004/0170685) as applied to claim 1 above, and further in view of Zscheeg (US 6,911,041). Eum et al. disclose a Nitinol stent but fail to disclose the weight percent of nickel based on the total composition of the alloy. Zscheeg disclose that it

is well known in the art that Nitinol comprising 54.5 to 57 % weight percent nickel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum weight percent of nickel, since it has been held that discovering the optimum value of a result effect variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

3. Claim 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) and Carpenter et al. (US 2004/0170685) as applied to claim 1 above, and further in view of Hossainy et al. (US 6,153,252). Carpenter et al. disclose the drug coating has multiple layers, but fails to disclose different degradability rates. Hossainy et al. disclose a drug coating comprising a polymeric resin is a biodegradable polymer having different degradability rates in order to control the release of drugs at various rates and times or to release multiple drugs with different pharmaceutical behaviors, wherein the top layer delays release of a pharmaceutical agent in the lower layers (col. 7, ln. 17-55). It would have been obvious to provide a polymeric resin having different degradability rates in order to achieve the desired drug delivery.

Response to Arguments

Applicant's arguments with respect to claim 1 and 6-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
08/14/09

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734